Risk Factors For Surgical Site Infection After Elective Resection of the Colon and Rectum: A Single-Center Prospective Study of 2,809 Consecutive Patients

Reiping Tang, MD,* Hong Hwa Chen, MD,* Yung Liang Wang, MD,† Chung Rong Changchien, MD,* Jinn-Shiun Chen, MD,* Kuan-Cheng Hsu, MD,* Jy-Ming Chiang, MD,* and Jeng-Yi Wang, MD

From the *Colorectal Section and the †Department of Anesthesiology, Chang Gung Memorial Hospital, Linkou, Taiwan

Objective

To identify the risk factors for surgical site infection (SSI) in patients undergoing elective resection of the colon and rectum.

Summary Background Data

SSI causes a substantial number of deaths and complications. Determining risk factors for SSI may provide information on reducing complications and improving outcome.

Methods

The authors performed a prospective study of 2,809 consecutive patients undergoing elective colorectal resection via laparotomy between February 1995 and December 1998 at a single institution. The outcome of interest was SSI, which was classified as being incisional or organ/space with or without clinical leakage. A likelihood ratio forward regression model was used to assess the independent association of variables with SSIs.

Results

The overall SSI, incisional SSI, and organ/space SSI with and without clinical anastomotic leakage rates were 4.7%, 3%, 2%, and 0.8%, respectively. Risk factors for overall SSI were American Society of Anesthesiology (ASA) score 2 or 3 (odd ratio [OR] = 1.7), male gender (OR = 1.5), surgeons (OR = 1.3–3.3), types of operation (OR = 0.3–2.1), creation of ostomy (OR = 2.1), contaminated wound (OR = 2.9), use of drainage (OR = 1.6), and intra- or postoperative blood transfusion (1–3 units, OR = 5.3; \geq 4 units, OR = 6.2). However, SSIs at specific sites differed from each other with respect to the risk factors. Among a variety of risk factors, only blood transfusion was consistently associated with a risk of SSI at any specific site.

Conclusions

In addition to ASA score and surgical wound class, blood transfusion, creation of ostomy, types of operation, use of drainage, sex, and surgeons were important in predicting SSIs after elective colorectal resection.

Surgical site infection (SSI) is among the leading nosocomial causes of complications and increased medical expense.^{1–4} It is also a clinical outcome indicator of fundamental importance in elective surgery.^{2,5–7} In 1992, the Centers for Disease Control and Prevention (CDC)'s National Nosocomial Infections Surveillance (NNIS) system modified the definition of surgical wound infection slightly and changed the name to surgical site infection. SSIs are divided into incisional SSI and organ/space SSI.⁸ Elective colorectal resection is the most frequent procedure in colorectal surgery. Organ/space SSIs, including intraabdominal or pelvic abscess and anastomotic leakage, are dreaded complications that may occur after colorectal resection. The distinction between abdominal abscess with and without leakage is of clinical and pathogenetic importance, because their risk factors for SSI may be different. Anastomotic leakage depends, to a great deal, on surgical skills,⁹ whereas weight loss of 10% body weight may be associated with abdominal abscess.¹⁰ The risk factors for incisional and

Supported by National Science Council, Taiwan, ROC: NSC89-2314-B-182A-077.

Correspondence: Jeng-Yi Wang, MD, Colorectal Section, Chang Gung Memorial Hospital, 199, Tung Hwa North Road, Taipei, Taiwan. E-mail:W3625@adm.cgmh.com.tw

Accepted for publication January 5, 2001.

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organ/space SSIs may also be different. Drainage of the surgical area and ostomy may predispose a patient to incisional SSI rather than organ/space SSI. 11,12

In 1991, the CDC's NNIS system proposed a risk index consisting of scoring each operation by counting the number of risk factors present among the following: a patient with an American Society of Anesthesiologists (ASA) preoperative assessment score of 3, 4, or 5; an operation classified as contaminated or dirty-infected; and a prolonged length of operation. The NNIS risk index may provide a valid comparison of SSI rates among surgeons or among hospitals. There are limitations in predicting SSI risk after elective colectomy, because most of the patients undergoing such a procedure have an ASA score of 1 or 2 and undergo a clean-contaminated procedure. Additional risk factors, including patient and surgical factors, need to be identified.

The primary goal of this prospective study was to identify the risk factors for SSI at each specific site in patients undergoing elective colorectal resection.

METHODS

The Chang Gung Colorectal Surgical Outcome Program was a single-center, prospective study of risk-adjusted surgical outcomes. All the patients undergoing surgery via laparotomy on the Colorectal Section of Chang Gung Memorial Hospital between February 1995 and December 1998 were admitted to this program. All operations were performed or supervised by one of seven attending surgeons. Endoscopic operations or operations only via the rectum or perineum were excluded.

Demographic and clinical variables were recorded at admission. Data collected included sex, age, presence of any coexisting diseases, history of previous laparotomy, weight loss, preoperative albumin and hemoglobin values, preoperative stay (days), operating surgeon, timing of operation, type of operation, additional surgical procedures, use of surgical drains, surgical wound class, duration of operation, colon preparation, administration of perioperative antibiotics, and type and amount of perioperative blood transfusion. Outcome variables included incisional SSI (superficial or deep), space/organ SSI (intraabdominal/pelvic abscess, peritonitis), anastomotic insufficiency, postoperative fever, postoperative complications, death, cause of death, and length of postoperative stay. All information was recorded by five surgical nurses on a prepared sheet, then translated into a numeric code for the computer.

For all the elective procedures, preoperative bowel preparation was achieved by use of an oral laxative, oral antibiotics (nitroimidazole), and either a Fleet enema or tap water rectal irrigation. The regimen of parenteral antibiotic administration (type, timing, and duration) was at the discretion of the surgeon. None of the surgeons administered repeated doses of a prophylactic antibiotic during an operation of long duration. No routine preoperative shaving was done. Other perioperative care was standard for all patients.

Abdominal incisions were closed with #1 polydioxanone (PDS) monofilament absorbable sutures for the fascia and absorbable or nonabsorbable sutures for the skin. The skin was closed primarily for all cases. Antibiotics were not applied to the wound, and subcutaneous drains were not used.

The attending surgeon and/or one of five surgical nurses inspected and evaluated the wounds daily during the hospital stay. All the patients were prospectively followed up for at least 4 weeks after surgery for the development of an SSI or other postoperative complications, either in the hospital or as an outpatient.

Inclusions and Exclusions

All operations performed electively and involving a resection of the colon and rectum were eligible for inclusion. Colostomy closure with wedge resection or segmental resection was excluded. In this prospective study, 2,809 consecutive patients undergoing elective colectomy were included.

Dependent Variables

The outcome of interest was SSI, defined according to the CDC's NNIS system. By these criteria, SSIs are classified as being either incisional (superficial or deep) or organ/ space. Criteria for a superficial incisional SSI were an infection occurring at the incision site within 30 days after surgery that involved only the skin and subcutaneous tissue and at least one of the following: purulent drainage from the incision; an organism isolated from a culture of fluid from the superficial incision; incisional pain, tenderness, localized swelling, redness, or heat, and the wound was opened; and a diagnosis of superficial incisional SSI made by the surgeon. Criteria for a deep incisional SSI were an infection related to the surgical procedure occurring within 30 days after surgery and at least one of the following: purulent drainage from the deep incision; the incision spontaneously dehisced or was deliberately opened when the patient had the previously described signs and symptoms of infection; and a diagnosis of deep incisional SSI made by the surgeon. In this study organ/space SSI was divided into intraabdominal/pelvic abscess without evidence of clinical anastomotic leakage (an intraperitoneal or pelvic collection of pus diagnosed by ultrasonography, computed tomography, or laparotomy) and clinical anastomotic leakage. Intraabdominal/ pelvic abscess near the leakage sites was reported as clinical anastomotic leakage.

Independent Variables

Patient Characteristics

Patient age was assessed as both a categorical variable (younger than 56 years, 56–75, older than 75) and a con-

tinuous variable. Patient characteristics included history of appendectomy; history of cholecystectomy; history of oophorectomy/hysterectomy; history of colorectal surgery; diabetes requiring medications; hypertension requiring medications, cardiac disease, liver disease including liver cirrhosis and chronic hepatitis; lung disease (chronic obstructive pulmonary disease, asthma); history of cerebrovascular accident; other medical illness not listed above; weight loss of more than 10% body weight (or 5 kg or more if body weight unknown) in recent 6 months; and ASA scoring conducted by the anesthesiologist immediately before surgery. Anemia was defined as a serum hemoglobin level of less than 10 g% at admission. Serum albumin (g%) was categorized in four levels: less than 3.0, 3.0 to 3.4, 3.5 to 3.9, and more than 4.0. Delay of operation was defined as the time from the date of admission to the date of operation and was assessed as a categorical variable (<3, 3-7, 8-14, >14 days).

Surgical Variables

Bowel preparation (including mechanical preparation and oral nitroimidazole 2 g h.s. before the day of surgery) was uniform and routine for elective operations. However, the regimen of parenteral antibiotic prophylaxis differed among surgeons. One surgeon preferred single-dose prophylaxis with a 500-mg intravenous bolus of cefazolin after induction of anesthesia. The other surgeons used different combinations of antibiotics before surgery and for a short period (1–5 days) after surgery. For comparison, the type of antibiotics was categorized as cephalosporins (cefazolin, cephalothin, cefamandole, and cefuroxime), aminoglycosides (gentamicin, netilmicin), metronidazole, and other (e.g., vancomycin). All the four types of cephalosporins used in this study are not active against Bacteroides fragilis according to the Sanford Guide to Antimicrobial Therapy (29th ed., 1999). Two variables were created within the dataset, one of which separated patients into two groups: those who received single-dose regimens and those who received multidose regimens. The other divided patients according to the spectrum of antimicrobial activity into those with antibiotic prophylaxis against both enteric Gram-negative organisms and anaerobes (including B. fragilis) and those not.

Surgeons reported the efficacy of colon preparation based on the nature of the residue (formed stool, liquid stool, clear mucus, and no residue) inside the bowel when it was opened. Clear mucus and no residue were classified as good colon preparation.

Surgical wounds were classified as clean-contaminated (bowel was opened without spill of contents; class 2) or contaminated (gross spill occurred or inflammation without pus formation was encountered; class 3) according to the classification of the National Research Council.

Surgical procedures included colectomy (right hemicolectomy, left hemicolectomy, partial colectomy/segmental colectomy), anterior resection, abdominoperineal resection, total/subtotal colectomy, and Hartmann's procedure. Addi-

tional procedure included colostomy/ileostomy, opening of gastrointestinal tract (e.g., gastrectomy, small bowel resection), opening of genitourinary tract (e.g., partial cystectomy, hysterectomy), incidental appendectomy, other procedures (e.g., partial hepatectomy), and use of drainage. The length of the operation was defined as the time from first skin incision to wound closure.

Blood transfusion was defined as an infusion of packed red blood cells or whole blood. One unit of blood transfusion was equated to 250 mL whole blood.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 10.0, SPSS Inc, Chicago, IL). The univariate relation between each independent factor and SSI was tested using the Student t test for the continuous variable (age) and two-tailed Fisher exact test or chi-square test for categorical variables. All means are expressed as \pm standard deviation. P < .05 was considered significant. To test the independence of the risk factors for SSI, the significant variables (P < .05) in the univariate analyses were entered into a multivariate logistic regression model with likelihood ratio forward selection with a criterion of $P \le .05$.

RESULTS

A total of 3,100 patients underwent colorectal surgery via a laparotomy during the 47-month period. Elective colorectal resection was performed on 2,809 patients (91%), who make up the study group. Patients ranged in age from 15 to 97 years (mean 61 \pm 14). There were 1,327 (47%) women and 1,482 (53%) men. Single-dose antibiotic (cefazolin) prophylaxis was given in 15% of the patients. More than half of the patients (59%) received perioperative prophylaxis with multiple-dose triple antibiotics (cephalosporins, gentamicin, and metronidazole). The range of the mean length of various operations was 3 to 4 hours. Right hemicolectomy had the shortest mean length of operation (3.1 \pm 0.9 hours), abdominoperineal resection the longest (4.1 \pm 1.1 hours). Of 2,809 patients, 134 (4.7%) had a diagnosis of SSI (all incisional and space/organ SSIs were grouped together). A total of 83 (3.0%) patients had incisional SSIs, 35 had deep incisional SSIs (including 9 with fascia necrosis or wound evisceration), and 48 had superficial incisional SSIs. A total of 23 (0.8%) had a diagnosis of intraabdominal/ pelvic abscess without clinical leakage (7 requiring laparotomy and 16 requiring percutaneous drainage and/or systemic antibiotic treatment). Among 2,491 cases with anastomosis (excluding abdominoperineal resection and Hartmann cases), 49 (2%) developed clinical anastomotic leakage.

Univariate Analysis

Eight variables relating to patient characteristics were found to be associated with overall SSI (Table 1) by uni184 Tang and Others Ann. Surg. • August 2001

Table 1. PATIENT CHARACTERISTICS BY SURGICAL SITE INFECTION

		Inc	Incisional		Space		akage	Total	
	Total No.		P		P		P		P
		%	Value	%	Value	%	Value	%	Value
Sex			.108		.105		.019		.011
Female	1,327	2.4		.5		1.1		3.7	
Male	1,482	3.4		1.1		2.3		5.7	
Age (yr)	, -		.218		.490		.844		.189
<56	842	2.5		.6		1.5		3.9	
56–75	1,610	3.4		1.0		1.9		5.4	
>75	357	2.0		.6		1.7		3.9	
Medical illness*									
Diabetes	294	5.1	.022	2.0	.027	2.7	.176	8.2	.004
Hypertension	510	2.9	.397	1.4	.125	7.1	.125	5.7	.830
Cardiovascular disease	159	5.0	.111	1.9	.138	3.1	.197	8.8	.014
Liver disease	87	5.7	.118	1.1	.516	.0	.404	5.7	.664
Lung disease	99	3.0	.964	1.0	.563	2.0	.691	6.1	.540
Cerebrovascular	78	9.0	.001	1.3	.478	5.1	.045	11.5	.004
accident history	70	5.0	.001	1.0	.470	0.1	.040	11.0	.004
Other disease	429	3.5	.472	1.2	.381	2.8	.070	6.8	.036
ASA score	423	0.0	.011	1.2	.563	2.0	.007	0.0	.004
1	1,138	1.8	.011	.6	.505	1.0	.007	3.2	.004
2	1,656	3.7		1.0		2.6		5.2	
3	1,030	.0		.0		7.1		6.7	
	10	.0	.446	.0	000	7.1	.260	0.7	.361
Anemia Absence	2,226	2.8	.440	.6	.029	1.9	.200	4.6	.301
	,								
Presence	583	3.4	000	1.5	00	1.2	177	5.5	000
Albumin (g%)	100	10.0	.000	0.0	.09	0.4	.177	10.0	.000
<3.0	130	10.8		2.3		3.1		12.3	
3.0–3.4	313	3.8		1.3		3.2		7.3	
3.5–3.9	732	2.7		1.1		1.6		4.5	
≥4	1,565	2.2		.4		1.4		3.8	
Unknown	69	4.3		1.4		1.4		4.3	
Loss of 10% body weight			.944		.002		.814		.503
Absence	2,007	2.9		.4		1.7		4.5	
Presence	652	2.9		1.7		1.8		5.4	
Unknown	150	3.3		2.0		2.0		6.0	
Delay of operation (days)			.758		.824		.001		.016
<3	858	2.9		.8		2.0		5.0	
3–7	1,551	2.8		.8		1.5		4.3	
8–14	333	3.6		.9		1.2		5.1	
>14	67	4.5		1.5		7.5		11.9	

ASA, American Society of Anesthesiology.

variate analysis. Patients with diabetes, a history of cerebrovascular accident, a lower serum albumin level, or a higher ASA score had a greater frequency of incisional SSIs than those without. Diabetes, anemia, or a loss of more than 10% body weight was associated with a higher incidence of abscess without leakage. Male patients, or patients with a history of cerebrovascular accident, with a higher ASA score, or with a prolonged delay of operation had a higher leakage rate.

Table 2 shows that the univariate significant surgical variables were similar among various types of SSI. Individual surgeon rates ranged from 1.2% to 5.9% for incisional SSI, 0.4% to 1.7% for space SSI, 0.6% to 3.5% for organ

SSI, and 2.2% to 9.1% for overall SSI. Hartmann's procedure and total/subtotal colectomy were associated with the highest SSI incidence. When perioperative blood transfusion was categorized according to timing of transfusion, preoperative transfusion was not associated with a higher SSI incidence (data not shown). Antimicrobial prophylactic regimen (combination of prophylactic agents or number of antibiotic doses) was not significantly associated with SSI.

Multivariate Analysis

Table 3 presents the 14 variables found to be associated with SSIs in the multivariate regression models. The risk

^{*} Comparison between presence vs. absence of each medical illness.

Table 2. SURGICAL VARIABLES BY SURGICAL SITE INFECTION

		Incisional		Space		Leakage‡		Total	
Variables	Total No.	%	<i>P</i> Value	%	<i>P</i> Value	%	<i>P</i> Value	%	<i>P</i> Value
Preoperative									
Colon preparation			.004		.015		.015		.000
Good	1,888	2.3		.5		1.3		3.5	
Not good	921	4.0		1.4		2.6		6.9	
Antibiotic dosing			.083		.562		.226		.071
Single	426	1.6		.5		.9		3.1	
Multiple	2,383	3.2		.9		1.9		5.1	
Parenteral antimicrobial activity*	,		.340		.354		.118		.776
Partial coverage	808	2.5		.5		2.4		5.0	
Full coverage	2,001	3.1		.9		1.5		4.7	
Operative	_, -,								
Surgeon			.003		.548		.040		.000
A	275	1.8	.000	.4	10 10	1.3	10.10	2.5	.000
В	300	2.7		1.0		1.9		5.0	
C	363	1.9		1.7		.6		2.8	
D	403	1.2		.7		.9		2.2	
E	427	3.1		.9		2.0		5.5	
F	422	5.9		.7		3.8		9.1	
G	619	3.2		.5		2.4		5.0	
Operation	010	0.2	.000	.0	.000	2.7	.022	0.0	.000
Colectomy	609	2.6	.000	.7	.000	.7	.022	3.4	.000
Anterior resection	1,704	2.3		.6		2.4		4.7	
Abdominoperineal resection	222	2.7		.0				2.7	
Total/subtotal colectomy	178	7.3		2.8		2.2		10.1	
Hartmann	96	8.3		4.2				9.4	
Additional procedure†	30	0.0		7.2				0.4	
Ostomy	541	6.3	.000	1.3	.172	2.0	.568	7.9	.000
Gastrointestinal	132	3.8	.563	1.5	.295	.0	.170	4.5	.901
Genitourinary	132	7.6	.001	2.3	.090	5.3	.001	12.1	.000
Appendectomy	1.678	2.7	.298	2.3 .7	.242	1.8	.611	4.5	.465
Use of drainage	1,490	3.8	.004	., 1.1	.111	2.9	.000	6.7	.000
Other procedure	404	3.7	.331	1.7	.028	2.9	.105	7.2	.014
·	404	3.7	.000	1.7	.020	2.1	.002	1.2	.000
Length of operation (h) ≤2.0	212	1.9	.000	1.4	.220	.0	.002	2.8	.000
2.1–3.0	1,114	1.2		.6		1.3		2.8	
3.1–4.0	901			.6		1.6			
		3.9						5.2	
>4.0	582	5.3	.000	1.4	101	3.4	.019	8.6	000
Surgical wound class	0.740	0.7	.000	0	.461	1.6	.019	4.4	.000
2	2,749	2.7		.8		1.6		4.4	
3	60	15.0	000	1.7	000	6.7	000	21.7	000
Blood transfusion§	1 007	4 7	.000	_	.000	_	.000	0.4	.000
0 unit	1,997	1.7		.5		.6		2.4	
1–3 units	430	3.7		.7		1.6		5.6	
≥4 units	382	8.6		2.9		7.9		16.2	

^{*} Parenteral antibiotics grouped into those (full coverage) having activity against both enteric gram-negative organisms and anaerobes (including *Bacteroides fragilis*) and those not (partial coverage).

factors for overall SSI were a higher ASA score, male, individual surgeon, Hartmann's operation or total/subtotal colectomy, creation of ostomy, contaminated wound class, the presence of drainage, and blood transfusion. The factor associated with the highest odds ratio was blood transfusion. A dose-response relationship was noted in the associ-

ation between blood transfusion and SSIs at specific sites and overall SSI. The strongest risk factors associated with incisional SSI were wound class and creation of ostomy. Statistically significant factors associated with anastomotic leakage were ASA score, anterior resection by sex, the presence of drainage, and blood transfusion.

[†] Comparison between presence vs. absence of each additional procedure.

[‡] Abdominoperineal resection and Hartmann's procedure were excluded.

[§] Intraoperative and postoperative blood transfusion.

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Table 3.	SURGICAL	SITE	INFECTION	ACCORDING	TO	PATIENT	AND	SURGICAL
			CHARA	CTERISTICS				

				Organ/				
	Incisional SSI		Without Leakage		With Leakage		Overall SSI	
Variables*	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Patient Characteristics								
ASA score 2 vs. ASA score 1	1.9	(1.1–3.2)			2.5	(1.3–5.0)	1.7†	(1.1–2.5)
Albumin <3 g%	2.3	(1.1-4.7)						
Diabetes			3.5	(1.3 - 9.4)				
Weight loss > 10%			3.1	(1.3 - 7.9)				
Male vs. female							1.5	(1.0-2.2)
Surgical Characteristics								
Surgeons#							1.1 -3.7†	
Operative procedures**	1.9-7.5†						2.2-9.5†	
Creation of ostomy	2.9‡	(1.6-5.3)					2.1†	(1.3-3.6)
Operative time $>$ 3 h	2.6†	(1.4-4.8)						
Wound class 3 vs. 2	4.0†	(1.6-8.9)					2.8†	(1.3-5.7)
Anterior resection by sex					2.7†	(1.4-5.0)		
Use of drainage					3.6†	(1.5-9.0)	1.6	(1.0-2.5)
Blood transfusion††								
1–3 units	1.5§	(0.8-2.9)	1.5§	(0.4 - 6.0)	2.4§	(0.9-6.5)	2.0	(1.1-3.3)
≥4 units	2.8‡	(1.6-4.9)	5.1†	(1.8-14.5)	15.2‡	(7.4-31.1)	6.2‡	(4.2-10.2)

SSI, surgical site injection; OR, odds ratio; 95% CI, 95% confidence interval; ASA, American Society of Anesthesiology.

Each OR significant at p < .05 except \dagger significant at p < .01, \ddagger significant at p < .001, and \S nonsignificant.

DISCUSSION

This series of postoperative SSIs is the largest singlecenter prospective study to date in colorectal surgery. We used current standardized CDC definitions of SSI that included infections of the incision as well as space/organ.⁸ Our data suggested that the risk factors for incisional and organ/space SSI with and without leakage are different from each other.

The only risk factor shared by all three site-specific SSIs was intra- or postoperative blood transfusion. In fact, this risk factor was also the most important factor among all variables in determining postoperative incisional, space/ organ, or overall SSI in our study. Allogeneic blood transfusion induces immunosuppression and predisposes to postoperative infection. An increased incidence of postoperative infection was observed in recipients of allogeneic transfusions in observational studies 11,17–19 and two randomized trials conducted by Jensen et al and Heiss et al, 4 but not some retrospective studies, 20,21 or one larger trial. Allogeneic leukocytes have a critical role in the induction of transfusion-induced immunosuppression. 14,23–30 In agreement with previous findings, 11 the present results also con-

firmed the notion that the only deleterious transfusion effect was seen in intra- or postoperative transfusion (rather than preoperative transfusion). This implies that the effects of blood transfusion might be, at least in part, surrogates for other risk factors, which are difficult if not impossible to measure in the clinical setting.

The use of prophylactic antibiotics in colorectal surgery has been proven to reduce the infection rate and the surgical death rate when compared with no-treatment controls. 31,32 Controversy persists regarding the choice of agent, the duration of administration, and the choice of single-drug or combination regimens. 33,34 There were no attempts to standardize the choice of antibiotics, the timing, or the duration of prophylaxis before initiation of this program. We found no difference in the SSI rate among regimens of antibiotic prophylaxis, which may be partly explained by the fact that all the patients received anaerobic coverage with oral nitroimidazole. Our results, together with those of previous studies, suggest that a single dose of preoperative antibiotic is sufficient for surgical prophylaxis when the operation is completed within 3 hours, 35-37 and routine prophylaxis should be administered as close to the time of induction of

^{*} All were dummy variables except # were categorical variables.

[#] ORs (95% CI) of overall SSI were 1.1 (0.4–3.1), 2.4 (1.0–5.7), 1.1 (0.4–2.9), 2.5 (1.1–5.6), 2.7 (1.2–6.1), and 3.7 (1.7–8.1) for surgeons A, B, C, E, F, and G respectively, when using surgeon D as a reference category.

^{**} ORs (95% CI) of incisional and overall SSIs were 3.4 (1.3–9.1) and 4.8 (1.8–12.7), 4.1 (1.4–12.4) and 4.4 (1.5–12.6), 7.5 (2.5–22.1) and 9.5 (3.2–27.7), and 1.9 (0.6–6.2) and 2.2 (0.7–7.2) for anterior resection, colectomy, total/subtotal colectomy, and Hartmann's operation respectively, when using abdominoperineal resection as reference.

^{††} Using no intra/postoperative blood transfusion as a reference category.

anesthesia as possible to provide the best chance for appropriate tissue levels above the minimum inhibitory concentration for potential bacterial contamination. ^{18,38}

Our incisional SSI rate of 3% is the lowest among studies limited to colorectal surgery, with reported rates of SSI ranging from 3% to 30%. ^{2,32,39-43} The degree of bacterial contamination is fundamental to the risk of incisional SSI. Our results showed that the incisional SSI rate for procedures with contaminated wound class was 3.8 times that for procedures with clean-contaminated wound class. The National Research Council (1964) laid the foundation for a system of surgical wound classification ⁴⁴ that has been confirmed by numerous studies. ^{13,18,45-47}

In agreement with previous findings, ^{5,13,18,42,46} the present data indicated that a length of operation of more than 3 hours is a risk factor for incisional SSI. Increasing the length of procedure theoretically increases the susceptibility of the wound by increasing bacterial exposure and the extent of tissue trauma (more extensive surgical procedure)⁴⁶ and decreasing the tissue level of the antibiotic. This finding supports the notion that the administration of an additional dose of antibiotic in lengthy procedures (e.g., >3 hours) might be effective in reducing the overall SSI rate. ^{39,42}

Some previous studies reported the association between incisional SSI and the individual surgeon. 5,48 The wide variation of SSI rates among individual surgeons is not likely to be explained by a biased case mix, because our hospital is a mixture of a primary and tertiary referral medical center that has a very high case volume. Major case mix differences in the types of operation conducted by the surgeons were not observed. Although fastidious surgical technique is recognized easily, it is difficult to measure. The surgeon assumes responsibility for the surgical procedure, avoidance of hematoma, and the need for a drain. In this way, the surgeons can modulate local and systemic host defense. 18,18,49–51

The routine use of a defunctioning colostomy at anterior resection is controversial. Because the present data and those of others suggested the creation of a stoma is not a protective factor for clinical anastomotic leakage but is an independent risk factor for incisional and overall SSIs, it is justified to create a protective stoma only after sphinctersaving resection for rectal cancer for anastomoses situated at or less than 5 cm from the anal verge, particularly for men and obese patients. ^{52–56}

Diabetes and weight loss were two factors important in organ/space SSI without leakage. Despite well-documented deficiencies in the defense mechanisms of patients with diabetes, the results of our study suggest that these deficiencies appear to place patients at an increased risk for organ/space SSI rather than incisional SSI. The results of one previous study also showed that patients with a weight loss of 10% had significant physiologic impairment and a higher incidence of septic complications (but not incisional SSI).

The overall incidence of clinical anastomotic leakage in the present study was 2%, but the incidence varied between surgeons (from 0.6% to >3.8%). The rate was similar to the reported rates of 1.8% to 5%.57-60 Anastomotic site, ^{56,58,60–62} timing of operation, ^{58,60,63} forms of reconstruction,⁵³ and surgeons⁹ should be considered before a valid comparison of leakage rate can be made among studies. Use of a drain was associated with a significantly higher prevalence of anastomotic leakage in this study. Because we did not use a drain routinely for colorectal anastomoses, a possible reason for the higher leakage rate associated with a drain may be that a drain was more frequently used in a difficult (hence inadequate hemostasis) or distal anastomosis. The incidence of leakage is higher when the anastomosis is distal.^{54,64} Experimental work with bowel anastomosis, especially colonic anastomosis, suggests that prophylactic drainage increases the risk of infection and leakage, possibly as a result of the foreign body effect of a drain. 65,66 A previous study on the basis of culture results also showed that there is a marked increase in the frequency of contaminated drain tips after 24 hours after total joint arthroplasty.⁶⁷ A clinically significant benefit of routine drainage of colon and rectal anastomoses in reducing the leakage rate has not been confirmed. 57,58,68,69 These findings, together with ours, suggest that wound drains are highly implicated in the potential pathogenesis of SSI, and drainage may be useful only in situations in which drainage is therapeutic, such as inadequate hemostasis.

Because of the single-center nature of our study, we could minimize interhospital variations, ⁷⁰ including observer differences, differences between patient groups, and different environmental factors (e.g., operating room discipline, sterility of instruments, handwashing, use of gloves and drapes, skin preparation, and aseptic technique).

Several important limitations of this study should be emphasized. First, we did not have a single person perform all the direct examinations of any suspicious SSI. Because there are marked differences in the tendency of surgeons to make a diagnosis of SSI,71 in our program we did not allow a surgeon's diagnosis alone for the diagnosis of incisional SSI. Surgical wound surveillance was carried out by five surgical nurses who directly observed the surgical wound as part of the process of determining the presence or absence of infection. Second, other factors may have influenced the patients' susceptibility to SSI, such as tobacco use, 72 obesity, 54,73 arterial hypoxemia, hypovolemia, and the vasoconstriction resulting from pain-induced stress. 73-75 Misclassification of variables in this study was nondifferential. We may conclude that this misclassification probably weakened the association between SSI and independent factors.

In summary, our results suggest that blood transfusion, surgical wound class, creation of ostomy, types of operation, ASA score, use of drainage, sex, and surgeon were all important in predicting overall SSI risk after elective resection of the colon and rectum. When assessing risk factors for SSI, the distinction between incisional SSI and organ/space SSI with or without leakage is of clinical and pathogenetic importance because the risk factors differ from each other.

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Acknowledgments

The authors thank Professor Lin Lin Hsieh for help with the statistics and nurse specialists Ms. Yao-Chi Chen, Yu-Chen Chen, Chiou-Mei Liu, Chia-Hui Kao, and Ya-Chuan Wang for direct wound observations and data recording.

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